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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,081	12/11/2003	Jingyue Ju	0575/68576-A/JPW/AJM/BJA	1586

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EXAMINER	
STAPLES, MARK	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,081	JU ET AL.	
	Examiner	Art Unit	
	Mark Staples	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7-11,13,14,17,18,33-35,39,41,43,44,and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-3, 7-11, 13, 14, 17, and 18, drawn to methods for covalently affixing a biomolecule to a second molecule with one molecule having an azido group and another biomolecule having an alkynyl group, classified in class 536, subclass 25.3.

   II. Claims 33-35, 39, 41, 43, and 44, drawn to methods for covalently affixing a biomolecule to a solid surface having an alkynyl group, classified in class 536, subclass 25.3.

   III. Claim 47, drawn to a method for covalently affixing a biomolecule to a solid surface having an azido group, classified in class 552, subclass 1.

Inventions I and II are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, are mutually exclusive, and are not obvious variants. Invention II differs from Invention I by affixing a biomolecule to a solid surface. Thus Invention I and II are mutually exclusive since affixing a biomolecule

to another biomolecule of Invention I does not overlap in scope with affixing a biomolecule to solid surface of Invention II. A solid surface is not a biomolecule, as disclosed in the specification:

> "[0054] In the first and second surface-related methods, the solid surface can be, for example, glass, silica, diamond, quartz, gold, silver, metal, polypropylene, or plastic. In the preferred embodiment the solid surface is silica. The solid surface can be present, for example, on a bead, a chip, a wafer, a filter, a fiber, a porous media, or a column."

Furthermore, there is nothing of record to show Inventions I and II to be obvious variants. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I and III are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the

inventions as claimed have a materially different design, are mutually exclusive, and are not obvious variants. Invention III differs from Invention I by affixing a biomolecule to a solid surface. Thus Invention I and III are mutually exclusive since affixing a biomolecule to another biomolecule of Invention I does not overlap in scope with affixing a biomolecule to solid surface of Invention III. A solid surface is not a biomolecule, as disclosed in the specification.

Furthermore, there is nothing of record to show Inventions I and III to be obvious variants. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper

Inventions II and III are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, are mutually exclusive, and are not obvious variants. Invention II differs from Invention III by affixing a biomolecule to a solid surface having an alkynyl group whereas Invention III affixes a biomolecule to a solid surface having an azido group. Thus Invention II and III are mutually exclusive since affixing by use of an alkynyl group Invention II does not overlap in scope with

affixing by use of an azido group of Invention III. An alkynyl group is chemically different and patenteable distinct from an azido group.

Furthermore, there is nothing of record to show Inventions II and III to be obvious variants. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper

Election of Species

2. This application contains claims directed to the following patentably distinct species for Groups I and II as follows.

Group I

I. **Second biomolecule is immobilized** (claim 10 in part)

A. Species of biomolecule

a. Nucleic Acid (claims 2 and 18 in part)

i. DNA (claim 3 in part)

b. Protein (claims 2 and 18 in part)

c. Carbohydrate (claims 2 and 18 in part)

d. Lipid (claims 2 and 18 in part)

B. Species of second molecule

a. Biomolecule (claim 7 in part)

b. Fluorescent Label (claim 7 in part)

c. Radiolabeled molecule (claim 7 in part)

d. Dye (claim 7 in part)

e. Chromophore (claim 7 in part)

f. Affinity label (claim 7 in part)

g. Dextran (claim 7 in part)

h. Antibody (claim 8 in part)

i. Biotin (claim 8 in part)

j. Streptavidin (claim 8 in part)

k. Metabolite (claim 8 in part)

II. **Neither the biomolecule nor the second biomolecule is immobilized** (claim 11 in part)

A. Species of biomolecule

a. Nucleic Acid (claims 2 and 18 in part)

i. DNA (claim 3 in part)

b. Protein (claims 2 and 18 in part)

c. Carbohydrate (claims 2 and 18 in part)

d. Lipid (claims 2 and 18 in part)

B. Species of second molecule

a. Biomolecule (claim 7 in part)

b. Fluorescent Label (claim 7 in part)

c. Radiolabeled molecule (claim 7 in part)

d. Dye (claim 7 in part)

e. Chromophore (claim 7 in part)

f. Affinity label (claim 7 in part)

g. Dextran (claim 7 in part)

h. Antibody (claim 8 in part)

i. Biotin (claim 8 in part)

j. Streptavidin (claim 8 in part)

k. Metabolite (claim 8 in part)

Group II

A. Species of biomolecule

a. Nucleic Acid (claim 34 in part)

i. DNA (claim 35 in part)

b. Protein (claim 34 in part)

c. Carbohydrate (claim 34 in part)

d. Lipid (claim 34 in part)

B. Species of solid surface

a. Glass (claim 39 in part)

b. Silica (claim 39 in part)

c. Diamond (claim 39 in part)

d. Quartz (claim 39 in part)

e. Gold (claim 39 in part)

f. Silver (claim 39 in part)

g. Metal (claim 39 in part)

h. Polypropylene (claim 39 in part)

i. Plastic (claim 39 in part)

C. Species of wherein solid surface is present on a

a. Bead (claim 41 in part)

b. Chip (claim 41 in part)

c. Wafer (claim 41 in part)

d. Filter (claim 41 in part)

e. Fiber (claim 41 in part)

f. Porous media (claim 41 in part)

g. Column (claim 41 in part)

The species are independent or distinct because each species is a patentably distinct molecule or substance. Each immunoassay is a patentably distinct method.

This application contains claims directed to the following patentably distinct species for Group I: immobilized or non-immobilized biomolecule(s), biomolecules, and second molecules; and for Group II: biomolecules, solid surfaces, and items where the solid surface is present.

The species are independent or distinct because each immobilized or non-immobilized biomolecule(s) is a structurally different and patentably distinct, each biomolecule is a structurally different and patentably distinct molecule, each second

molecule is a structurally different and patentably distinct molecule, each solid surface is a structurally different and patentably distinct, and each item where the solid surface is present is a structurally different and patentably distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 13, 14, 17, 33, 43, 44, and 47 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

For Group I, that means applicant must elect a single specified species of immobilized or non-immobilized biomolecule(s), biomolecule, and second molecule. For Group II, that means applicant must elect a single specified species of biomolecule, solid surface, and item where the solid surface is present. Specified means that a single molecule, substance, or item must be identified. For example, election of protein would be a single specified biomolecule.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these species are independent or distinct for the reasons given above and the species require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

4. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Close

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
Examiner
Art Unit 1637
September 12, 2006

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

9/14/06

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-3,7-11,13,14,17,18,33-35,39,41,43,44, and 47.